APR 2 1998

K990726

Special 510(k) Premarket Notification
Envy™ Guiding Catheter
COOK INCORPORATED

❑ 510(k) Summary

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235

Device:

Trade Name:	Envy™ Guiding Catheter
Proposed Classification Name:	Catheter, Intravascular, Diagnostic 21 CFR Part 876.1200 (74DO)

Predicate Devices:

The Envy™ Guiding Catheter, 4.0, 7.0 and 8.0 French, has the same intended use, materials of construction, and technological characteristics as the Envy™ Guiding Catheter, 6.0 French.

Device Description:

The Envy™ Guiding Catheter is manufactured using an inner layer of nylon tubing with stainless steel braiding and laminated with an outer layer of TFE tubing. This tubing is coated with a hydrophilic coating to enhance lubricity. This catheter is available in 4.0, 7.0 and 8.0 French outer diameter, various lengths and various curves to accommodate interventional cardiology procedures.

French Size	Inside diameter
4.0	.040-inch
7.0	.078-inch
8.0	.092-inch

This device can also be used with an inner catheter used for introduction. The inner catheter is manufactured using polyethylene tubing tapered to an .038-inch endhole with a hydrophilic coated distal tip. The length of the inner catheter corresponds to the guiding catheter length. The inner catheter is designed to introduce the guiding catheter over an 0.038-inch wire guide or through an appropriately sized sheath introducer.

❑ 510(k) Summary

Substantial Equivalence:

The Envy™ Guiding Catheter, 4.0, 7.0 and 8.0 French, is similar to many devices in commercial distribution for delivery of PTCA balloons and other various types of interventional cardiology devices. It is identical to the currently marketed Envy™ Guiding Catheter, 6.0 French, in overall configuration and indications. The Envy™ Guiding Catheter, 6.0 French, was cleared for commercial distribution on October 16, 1998, D.C.#K974774. The identical indications for use and technological characteristics of the Envy™ Guiding Catheter supports a determination of substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1999

Ms. April Lavender, RAC
Vice President
Regulatory Affairs
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K990726
Envy™ Guiding Catheter, 4.0, 7.0 and 8.0 French
Regulatory Class: II (Two)
Product Code: 74 DQY
Dated: March 3, 1999
Received: March 5, 1999

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Envy™ Guiding Catheter

Indications for Use:

Used for the delivery of PTCA balloons and other various types of interventional cardiology devices. They are intended for use by physicians trained and experienced in PTCA and interventional cardiology techniques. Not intended for cerebral vascular use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number_____